UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,636	10/20/2003	Patrick Rambaud	0501-1017-1	1794

466 7590 03/31/2010

YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

EXAMINER	
WHALEY, PABLO S	
ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
03/31/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/687,636	RAMBAUD, PATRICK	
	Examiner	Art Unit	
	PABLO WHALEY	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33,34 and 36-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33, 34, and 36-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 33, 34, and 36-43 are rejected. Claims 33, 34, and 36-43 are pending. Claims 1-32 and 35 are cancelled.

Objections

Claim 33 is again objected to because of the following informalities: Claim 33 (line 33) is grammatically incorrect, and should recite "…information that ~~are~~ is characteristic…" . Appropriate correction is required. The objection of claim 41 is withdrawn in view of applicant's amendment filed 01/08/2010.

Withdrawn Rejections

The rejection of claims 36-42 under 35 U.S.C. 101 is withdrawn in view of applicant's amendments filed 01/08/2010, which now require a computer system and a storage device for preserving and conditioning cells.

Claim rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims that depend directly or indirectly from claims 33 and 36 are also rejected due to said dependence.

This rejection is necessitated by amendment.

The term "optimized proportions" in claim 33 (5th line from the last) is a relative term which renders the claim indefinite. The term "optimized proportions" is not defined by the claim, the

specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In particular, the parameter of selected types of cells has been rendered indefinite by the use of the term "optimized proportions." Clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 33, 36, 37, 38, 39, 41, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5; English translation version), in

view of Barnhill et al. (US 6,248,063; Filed Dec. 22, 1997), and in view of Shortliffe et al., (In Proc. Seventh International Joint Conference on Artificial Intelligence, 1981, Vol. 60, pp. 876-881; IDS filed 09/12/2006).

This rejection has been modified to include claim 43 in view of applicant's amendment.

The instant claims are drawn to a method and system for managing batches of immunocompetent cells collected from human or animal subjects for their deferred use. The components of the invention include a storage device, collection device, status-characterizing device to determine identity data, a cell management processor for storing identity data, a personal library processor for constituting a personal library.

Lefesvre teaches batch management system for managing immunocompetent lymphocyte cells obtained from human subjects [p. 1, ¶1]. In particular, Lefesvre teaches one or more cryogenic storage sites wherein each batch of immunocompetent cells are collected, stored, and preserved for deferred use [p.2, ¶7, ¶8, p. 3]. The information collected for processing includes personal data relating to the subject, cellular identification data, immunity related information, and gene therapy protocol information [p.2, ¶8, p.2, ¶ 12, Fig. 1, p.3, p.4, ¶5]. Lefesvre teaches processing of blood to collect information indicative of patient health status [p. 1 and Fig. 1, p.3, ¶ 9], which shows a status characterization step of collecting information. A plurality of cellular processing centers are described for batch processing of immunoqualified cells [p.3, ¶1]. The centers provides means for communicating with storage sites, producing a personal library of immunoqualified lymphocyte cells, which inherently store immunity information, and identifying stored batches of cells in response to requests for treatments using said cells [p.3, ¶1, See also p.2, ¶ 2, p.4, ¶ 4]. Lefesvre provides a database that can be queried by a user to obtain information [p.3, last ¶]. Lefesvre teaches protocols for performing identification of cells and consulting a cell management database system[p.3, ¶1-¶3, p.4, ¶1], receiving requests for subject identity data [p.3, last ¶], and processing of the database based on patient specific requests [p.4, last ¶, p.4]. Lefesvre shows

a process for selecting and removing cells from a personal library according to deferred use protocols and components for re-using lymphocytes in the patient [p.4, ¶ 2, and p.4, ¶7 onwards], which shows selecting cells for extraction. Lefesvre describes steps for gathering personal data for processing at the time of re-use [p.4, ¶5]. The system makes possible the batch storage of cells in accessible and identifiable form for deferred use protocols including gene therapy protocols, restoring cellular immunity, gene therapy, genetic analysis, infection detection, etc. [p.2, ¶6, p.2, ¶ 12, p.4, ¶8, p. 3]. Lefesvre teaches checking operations of quality (i.e. checking for annihilation of antibodies) [p.4, ¶ 2]. Regarding the newly added claim, the overall management process includes storage centers that are controlled using software [p.3, ¶1, See also p.2, ¶ 2, p.4, ¶ 4].

Lefesvre does not teach an expert system wherein said information is entered in the form of biological items to which a set of rules stored in a knowledge base is applied, as in claims 33 and 36.

Lefesvre does not teach implementing into said expert system a process for determining a deferred use protocol comprising biological and technical indications required for cell processing before re-use of a batch of immunocompetent cells, as in claims 33 and 36.

Lefesvre does not teach a processor for processing identity data to determine parameters of a deferred use protocol for identified batches of immunocompetent cells, said processor configured on prescription of a re-use process, as in claims 33 and 36.

Barnhill teaches an expert system for receiving patient data from another location, processing the data to produce a diagnostic or prognostic value, and transmitting the result to another location [Abstract, Col. 7, ¶4, Fig. 12]. The expert system uses patient information, biomarkers, demographics, and physiological measurements information [Col. 7, ¶4, Fig. 13A]. Specific ranges for disease are described and used in the treatment recommendation process [Fig. 17].

Shortliffe teaches an expert system for clinical protocol management. In particular, the expert system (ONCOCIN) comprises a data-acquisition program (Interviewer) for obtaining and reviewing

patient data, and a consulting device (Reasoner) for providing recommendations on the appropriate tests and therapies (i.e. deferred use protocols) [p.877, Col. 2]. The Reasoner obtains data from a knowledge base that stores patient information, previous treatments, laboratory results, and protocol specific information [p.877, Col. 2, ¶2]. Specific rules for determining deferred uses are disclosed [p.879, Col. 1, Col. 2, Advice]. Standard procedures for determining parameters for protocol management and parameter values are also described [p.878, Col. 2, ¶4, p.879, Col. 2, Control]. The system is flexible and easily modified to address different types of protocols [p.881, Col. 1, ¶1, ¶2].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the cell batch management system of Lefesvre by using an expert system wherein said information is entered in the form of biological items to which a set of rules stored in a knowledge base is applied, as in claim 33, since Shortliffe shows a modifiable expert system that uses biological information and rules for making treatment recommendations (i.e. deferred use protocols) with predictable results, as set forth above, and since Lefesvre provides specific biological information and deferred use protocols for use with a processing system [p.2, ¶6, ¶8]. The motivation would have been to improve treatment recommendations with an automated consultation system that optimizes the use of patient data [Shortliffe, p.881, Section VII].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the cell batch management system of Lefesvre by implementing into said expert system a process for determining a deferred use protocol comprising biological and technical indications required for cell processing before re-use of a batch of immunocompetent cells, as in claim 33, since Barnhill provides an expert system for making recommendations using data from remote locations, as set forth above, and since Shortliffe shows a modifiable expert system that uses biological information for making treatment recommendations (i.e. deferred use protocols) with predictable results, as set forth above. The

motivation would have been to provide physicians with an improved system for data collection and decision making [Shortliffe, p.881, Section VII].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the cell batch management system of Lefesvre by processing identify data to determine parameters of a deferred use protocol, as in claim 33, since Lefesvre shows storing cells in identifiable form for deferred use protocols including gene therapy protocols, restoring cellular immunity, gene therapy, genetic analysis, infection detection, etc. [p.2, ¶6, p.2, ¶ 12, p.4, ¶8, p. 3], and since Shorliffe shows that parameters for determining deferred use protocols in protocol management systems are used with predictable results [p.877, Col. 2, ¶2, p.878, Col. 2, ¶4, p.879, Col. 1, Col. 2, Advice]. The motivation would have been to improve treatment recommendations with an automated consultation system that optimizes the use of patient data [Shortliffe, p.881, Section VII].

Claims 33-34 and 36-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5; English translation version), in view of Barnhill et al. (US 6,248,063; Filed Dec. 22, 1997), and in view of Shortliffe et al., (In Proc. Seventh International Joint Conference on Artificial Intelligence, 1981, Vol. 60, pp. 876-881), and further in view of Zanin et al. (WO/1997/045056; Publication Date: 12/4/1997) and Cha et al. (Physiol. Meas., 1994, Vol. 15, p. 129-137).

Lefesvre, Barnhill, and Shortliffe make obvious a method and system for managing batches of immunocompetent cells for deferred use, as set forth above.

Lefesvre, Barnhill, and Shortliffe do not teach a device for collecting bioelectronic information, as in claims 34.

Lefesvre, Barnhill, and Shortliffe do not teach bioelectronic information resulting from processing measures as in claim 40.

Zanin teaches a method and device for measuring, processing, and storing bio-electrical signals [Abstract, p.2, Fig. 1, p.6]. Collected and processed information includes parameters and data relating to various measured levels including pH [p.9, last ¶]. In addition, Zanin also teaches an expert system comprising control and interpretation software to provide the physician with tools for determining patient health status and reliable treatments [Abstract, p.3, Ref. claims 3 and 5].

Cha teaches a routine method for obtaining bioelectronic information by processing previously collected patient blood samples. The information includes resistance (i.e. resistivity) and reactance data [Abstract, Fig. 1, Section 3], as in claims 2, 21, and 34.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the cell batch management system taught made obvious by Lefesvre, Barnhill, and Shortliffe by collecting bioelectronic information, as in claims 34 and 40, since Zanin and Cha shows methods and devices for storing an processing bioelectronic data, as set forth above. The motivation would have been to improve patient care using a system adapted to receive and analyze bioelectronic data commonly used in patient health assessment, as suggested by Zanin [p.1, ¶3] and Cha et al. [p.136, ¶ 3and 4].

Claims 33, 34, and 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5; English translation version), in view of Barnhill et al. (US 6,248,063; Filed Dec. 22, 1997), in view of Shortliffe et al., (In Proc. Seventh International Joint Conference on Artificial Intelligence, 1981, Vol. 60, pp. 876-881), in view of Zanin et al. (WO/1997/045056; Publication Date: 12/4/1997), in view of Cha et al. (Physiol. Meas., 1994, Vol. 15, p. 129-137), and further in view of Tomoyasu (Applied And Environmental Microbiology, Jan. 1998, p. 376–382).

Lefesvre, Barnhill, Shortliffe, Zanin, and Cha make obvious a method and system for managing batches of immunocompetent cells for deferred use, as set forth above.

Lefesvre, Barnhill, Shortliffe, Zanin, and Cha do not teach a step for immunomagnetically selecting purified lymphocytes or monocytes, as in claim 42.

Tomoyasu teaches a method for immunomagnetically separating cells using Dynabeads [Abstract].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the cell batch management system taught made obvious by Lefesvre, Barnhill, Shortliffe, Zanin, and Cha by immunomagnetically selecting purified lymphocytes or monocytes, as in claim 42, since Tomoyasu shows conventional methods of immunomagnetic separation of cells, as set forth above. The motivation would have been to provide an improved method of separating cells using magnetic beads [Tomoyasu, p.379, Col. 1, ¶3, ¶4].

Response to Arguments

Applicant's arguments filed 01/08/2010 have been fully considered.

In response to applicant's argument that Shortliffe does not teach parameters of a deferred use and that the term "parameter" has been misinterpreted [p.16], it was acknowledged that Lefesvre does not teach processing identity data to determine parameters of a deferred use protocol for identified batches of cells, said processor configured on prescription of a re-use process, as in claims 33 and 36. Broadly interpreted, this limitation reads on any parameter that can be used in some type of protocol. Shortliffe teaches an information management system using parameter input data to make medical recommendations [p.877], wherein parameters are defined as representing the attributes of patients, drugs, test, etc. that are relevant for protocol management tasks within the scope of treatment of a subject. Therefore, Shortliffe reasonably satisfies the claim language for deferred use protocols. As pointed out in *In re Mott*, 190 U.S.P.Q. 536 (CCPA 1975), "Claims must be given broadest reasonable construction their

language will permit in ex parte prosecution, and applicant who uses broad language runs the risk that others may be able to support the same claim with a different disclosure."

In response to applicant's argument that it would not have been obvious to combine the teachings of Lefesvre, Barnhill, and Shorliffe, because Lefesvre is nonanalogous art and deals with immunocompetent cell management [p.17-18], it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Lefesvre shows storing immunocompetent cells in identifiable form for deferred use protocols that include gene therapy protocols, restoring cellular immunity, gene therapy, genetic analysis, infection detection, etc. [p.2, ¶6, p.2, ¶ 12, p.4, ¶8, p. 3]. Shorliffe shows that parameters for determining deferred use protocols that include patient treatment protocols [p.877, Col. 2, ¶2, p.878, Col. 2, ¶4, p.879, Col. 1, Col. 2, Advice]. Barnhill teaches an expert system for receiving and processing patient data to produce diagnostic reports and treatment recommendations, as set forth above. Therefore, Shorliffe and Barnhill are reasonably pertinent to the particular problem with which the applicant is concerned, expert systems for managing patient information and determining deferred use protocols.

In response to applicant's statement that the above references were inappropriately combined based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's statement of priority, this application has been granted the benefit of priority to application No. 09/685,961, filed Oct. 16, 2000, and French application 00 00804 filed Jan. 21, 2000. However, the Lefesvre reference cited above remains prior art under 35 USC 103.

In response to applicant's statements regarding US 6,415,201 (Lefesvre) [see pages 21-22], this reference was not cited as prior art and the instant application has not been granted the benefit of priority to US 6,415,201. Therefore applicant's arguments are moot.

For the above reasons, the examiner maintains that the above combination of references teaches and/or makes obvious the claimed limitations.

Notice of Change to Docketing of Requests for Continued Examination

Applicant is reminded of the change in docketing of Requests for Continued Examination set forth in the online OG Notice of 10 November 2009 (*1348 OG 254*; http://www.uspto.gov/web/offices/com/sol/og/2009/week45/TOC.htm#ref14).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached between 12pm-8pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner

Art Unit 1631

/PW/

/SHUBO (Joe) ZHOU/
Primary Examiner, Art Unit 1631